From: <u>Bill Jacobs</u>
To: <u>Denise Keyes</u>

Subject: RE: Rodent Bait Station
Date: 07/08/2009 01:22 PM

The same panel of adults would be used for all phases of adult testing (putting the station into use initially and refilling the station). They would have up to 30 minutes for the first part and up to 30 more for the second part.

Since I replied to your earlier message, there has been some discussion here about posting the modifications to the testing requirements. That may occur in the near future.

At this point, if I were in your shoes, I would advise my client to design the station so that it can be secured, preferably by more than one method, even though testing secured units is not to be required for the child tests. Stations that are secured in place when put into use are expected to remain in place. If the product has appropriate use directions, initial placements will be made in locations and at intervals appropriate for controlling the targeted pest, typically the house mouse. Especially if placed in areas where there is frequent human (and pet) activity, stations will be moved, likely to less use-appropriate locations. While humans might occasionally stub a toe on a secured station situated along a wall, they might involuntarily "skate" on an unsecured unit, especially if it has been moved away from its original placement location to a spot closer to the middle of a room. Voluntary interaction (play) by children seems likely to be more frequent, more intense, and more prolonged if the unit can be moved. Even with bait blocks in the unit, such activities might result in some of the bait escaping from it and in greater potential for it to be damaged (see paragraph 2.2 of Protocol 1.228). With unsecured stations, damage by dogs seems inherently more likely, with increased potential for injury (due to broken plastic) and/or exposure to the bait.

## ▼ "Denise Keyes" ---07/07/2009 10:45:27 AM---Dear Bill: Thank you for your response to my questions. It was very informative. I

From: "Denise Keyes" <denise@crr.net>
To: Bill Jacobs/DC/USEPA/US@EPA

Date: 07/07/2009 10:45 AM
Subject: RE: Rodent Bait Station

## Dear Bill:

Thank you for your response to my questions. It was very informative. I have some questions regarding #2 below. For the panel of adults, what is the test required? Do the adults have to secure the bait station (if applicable) and refill the bait station? If so, is the same panel of adults used for both parts of the test and is 30 minutes allowed for each? If there are publications that outline the decisions to change the protocols, where would I find this information?

Again, thank you for your assistance with these questions. I hope you had a wonderful  $4 \, \text{th}$  of July holiday.

Best regards,

Denise Keyes Child Related Research, Inc.

----Original Message----

From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov] Sent: Tuesday, June 30, 2009 12:27 PM

To: Denise Keyes

Subject: Re: Rodent Bait Station

This response is a follow-up to your e-mail message (attached) and our telephone conversation yesterday.

- The versions of Protocols 1.228 and 1.229 that were attached to the Rodenticide Risk Mitigation decision are the current versions of those protocols. However, some subsequent decisions affect what is to be required for testing ready-to-use rodenticide bait stations for aspects of tamper-resistance.
- 2. One panel of adults, ages 18-70, is all that is required for the adult-use test, which is needed for refillable bait stations. To provide results that are as representative as possible of the U.S. adult population, you should try to have approximately equal representation of male and female subjects and approximately equal representation of young, middle-aged, and older adults.
- Child testing is required to be done with stations that are not secured. However, also testing children with secured stations might provide useful feedback for your client.
- 4. Quality control is an important aspect of what the testing is to assess. Therefore, testing should be conducted on production models, with one unit being used per test. Prototypes often are made from different materials than are used for production models and may have subtle differences in the design and bonding of some components. experience, it is not unusual for prototypes to be more brittle than production models and for production models to be thinner/weaker in some places than prototypes. I would recommend doing some pilot testing with children of CRP-testing age and also with adults to identify potential problems with unit designs before production molds are made. If a unit were tested time and again, progressive damage to it from multiple subjects might create a situation in which the unit passes with all or nearly all subjects up to a point and then subsequently fails with all or most of them. Directed attention from 50 or more kids in succession would be a greater challenge from children than a unit is likely to face under actual use conditions. Protocol 1.228 includes a product-fatigue design feature for child tests with refillable units.

The station depicted in you e-mail message appears to have several ingenious design features. If children can figure out how to work the bait-tray mechanism and have the strength to do so, there could be a lot of failures, especially with children being tested in pairs.

I can't really judge from the pictures, but it looks like there might be easy reach-in access to the bait compartment via the rodent entrance holes and the tunnel between them. The baffles depicted would not seem to thwart child access from either entrance, unless all entrances and passages were too small for a child's hand to enter. If the bait is to be contained in the rear chamber of the slide-in tray and the mouse has to scale hurdles to get to the bait, reach-in access by children would be rendered more difficult, assuming this to be a mouse-sized station.

The projected legs clearly are designed for securing stations to substrates. It also would be a good idea for the unit to have a flat bottom so that securing it with two-sided foam tape would be a viable option, and one that did not require using 4 screws and making 4 holes. If the substrate is flat, clean, and relatively non-porous, two-sided foam tape can hold a bait station in place for years, assuming that there is a reasonable amount of setting time (~1-2 hours) before the first challenge. When it is time to remove the baiter, that can be accomplished with little or no damage to the substrate, provided that the person cuts through the foam with a something like a dinner knife and then rolls up the residual adhesive on the substrate using the thumb in the manner of making a mini snowman. I used two-sided foam tape to fasten a baiter to the corner of my former office in July of 1984. The tape held it in place through multiple office moves. When I had to

surrender the desk in April of 2006, the station was still there and still could not be pulled off of the desk with reasonable adult effort. However, the knife-and-snowman approach took it right off and left a clean desk top.

This unit has a rather toy-like appearance and might prove to be something of a kid-magnet, especially if production models come in multiple colors. Having a see-through top would have potential advantages and disadvantages. On the plus side, transparency would enable users to assess the amount and condition of bait remaining in deployed units and to determine at any time whether there is a mouse inside of it. A see-through feature also might influence some children in the direction of concluding that there is nothing of interest within the station. On the other hand, an opaque unit might be more attractive to rodents as a secure place in which to hide and feed and might influence some children away from trying to reach in if they did not know what was inside.

>   From:	
"Denise Keyes" <denise@crr.net></denise@crr.net>	
>   To:	,
>   Bill Jacobs/DC/USEPA/US@EPA    >	I
/>   Date:	I
06/29/2009 01:29 PM	
	I
Rodent Bait Station	
<u></u>	

## Dear Bill:

Thank you for taking the time to speak with me today regarding the testing of ready-to-use bait stations. As mentioned, I have been given permission from our client to the forward the pictures of the bait station to you. They have determined that the station is